REMARKS

These remarks are being made in response to the Office Action mailed in this application on March 31, 2004. Claims 9-16 are pending in this application, although claim 16 has been withdrawn from consideration. Reconsideration of this application is respectfully requested in view of the following remarks.

First, the restriction requirement has been maintained by the Examiner. For all the reasons given in their last response, applicants again request that the requirement be withdrawn.

Turning then to the action on the merits, applicants note that claims 9-11 and 13-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Winicov et. al., U.S. 4,271,149 ("Winicov"). Applicants traverse this rejection.

A feature of the present invention is to create a composition for a wound which delivers a regulated amount of iodine, as antiseptic, to the wound; that amount being high enough to be an effective antiseptic, yet low enough so as not to incur damage or toxicity in the tissue where the composition is applied. The toxic effects of high levels of iodine have been known in the prior art.

Unlike the invention of the present application, the focus of Winicov is to improve storage concentrations of iodine since art prior to Winicov was troubled with loss of iodine concentration over time. Winicov does not suggest or teach controlled release of iodine during use or application of a composition via control of the pH. Rather, Winicov simply seeks to use pH to improve shelf life and storage of the composition.

Next, Winicov teaches a solution of both iodate and iodide together, not kept separately. In the present application, an oxidant and the iodine are kept separately until application.

Further, the rejection appears to suggest that the solution of Winicov and the compositions of the present application are capable of identical performance. Certain embodiments of the present application, e.g., examples I and II, are compositions resulting in a gel or a film. Winicov, on the other hand, relates to the storage of aqueous iodine compositions. Such compositions would have different properties than gels and films. Consequently, it is a leap to conclude that the compositions of Winicov are capable of the ability to deliver a steady amount of iodine to a wound site, both by hour and over a period of three days, as in the instant application.

Thus, in the present application, the technical problem to be solved is to make a composition which delivers iodine to a wound at a rate which is high enough to provide effective antisepsis but which is low enough to avoid the problems of adverse reactions associated with high levels of iodine.

In Winicov et al., the compositions are intended for a very different use, *i.e.*, teat dips for dairy cows and hand washes. The components are not separated, but are held and stored together along with iodine. The iodate and iodide present in the composition are used for stability, to produce iodine during storage, to counterbalance the slow loss of iodine from the composition. (See, *e.g.*, column 2, lines 37-42, of Winicov et al.) There is no hint in Winicov et al. that this reaction, through control of pH, could be used to give a controlled release of iodine during product use. Thus, Winicov et al. is solely concerend with use of pH to give improved storage of the composition.

It is asserted in the Office Action that although certain of the claimed features are not expressly disclosed by Winicov et al., there is evidence in Winicov et al. for the features. Applicants disagree. There is nothing in Winicov et al. to suggest that the iodate/iodine reaction can be used as the means of generating iodine in the product in use. The compositions of Winicov et al. all contain iodine, and this is relied upon for efficacy. The longer lasting effect in Winicov et al. is directed solely to storage performance. Moreover, the levels of iodine in the compositions of Winicov et al. are too high for use in wounds for the reasons mentioned on page 1 of the instant application. Note, *e.g.*, that the compositions of the invention can result in amounts of free iodine available for wound treating at any time of at least 0.001% (see page 4 of the instant application), while the amounts noted in Winicov et al. are intended for teat dips for dairy cows and hand washes, and therefore are much higher.

For these reasons, applicants request that this rejection be withdrawn.

Claims 9 and 15 were then rejected under 35 U.S.C. 102(b) as being anticipated by Bentley et al., U.S. 5,128,136 ("Bentley"). Applicants traverse this rejection as well.

First, in one embodiment, Bentley teaches a composition with a pH of 5.5-7.5, for the purpose of applying a pH neutral solution. The instant application uses pH ranges of 4.5-6. Because the scale of pH is a ten-fold increase or decrease in the hydrogen ion concentration, these ranges are markedly different. It is well known that the slightest changes in pH can drastically alter any reaction, especially physiological processes. pH in the present application allows for a controlled release of iodine. Bentley does not teach a controlled release of iodine for treatment and the iodine reactions of Bentley and the instant application cannot be compared due to the highly different pH environments.

Second, where Bentley's composition includes iodide and an oxidizing agent, Bentley holds the iodide separate from the oxidizing agent. When they are combined, the pH of the solution is about 3.4. This is "to ensure optimum Iodine release" (Col. 7, line 41). That is not the goal of the

instant application. In fact, the instant application regulates a controlled deposit of iodine to the wound. It cannot be said that Bentley is capable of a controlled deposit of iodine, as the instant application points out that below pH 4.5 the rate of iodide ions being oxidized is too rapid and is likely to induce toxicity (see page 4, lines 12-15). As discussed above, when the iodide-oxidant solution in Bentley is combined with the collagen solution, the pH is neutralized and is not capable of controlled delivery of iodine to the wound.

For these reasons, applicants request that this rejection be withdrawn.

Finally, claims 12 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Winicov in view of Bentley. Applicants also traverse this rejection.

Winicov and Bentley are discussed above, and for those reasons neither teach nor suggest the claimed invention. Further, there is nothing in Winicov to suggest that it would be appropriate to combine its teachings with those of Bentley. For a combination to be appropriate, there must be some reason or suggestion, other than applicants' disclosure, for the combination. There is no such reason in either Winicov or Bentley. Even if the teachings were combined, one still would not arrive at the instant invention. There is nothing in either Winicov or Bentley, whether taken alone or together, that suggests that the reaction of iodate and iodide, through control of pH, could be used to give a controlled release of iodine during product use.

For these reasons, applicants request that this rejection be withdrawn.

In view of the foregoing, withdrawal of the rejections of the claims, reconsideration of the restriction requirement and the application, and allowance of the application with claims 9-16 are all respectfully requested.

Respectfully submitted,

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